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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR APPLICATION NO. **FILING DATE** 09/349,713 07/08/99 BUCHHOLZ MERCK-1900 **EXAMINER** HM12/0815 MILLEN WHITE ZELANO & BRANIGAN PC SHARAREH, S ARLINGTON COURTHOUSE PLAZA 1 PAPER NUMBER ART UNIT 2200 CLARENDON BOULEVARD STE 1400 ARLINGTON VA 22201 1619 **DATE MAILED:** 08/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No. 09/349,713

Examiner

Group Art Unit

Buchholz et al

Shahnam Sharar h 1619 Responsive to communication(s) filed on <u>Jul 8, 1999</u> ☐ This action is FINAL. ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quay/1935 C.D. 11; 453 O.G. 213. A shortened statutory period for response to this action is set to expire ______3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Disposition of Claim X Claim(s) 1-15 _____is/are pending in the applicat Of the above, claim(s) ______ is/are withdrawn from consideration Claim(s) ______ is/are allowed. Claim(s) is/are objected to. ☐ Claims ______ are subject to restriction or election requirement. **Application Papers** ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. ☐ The drawing(s) filed on ______ is/are objected to by the Examiner. ☐ The proposed drawing correction, filed on ______ is ☐ approved ☐ disapproved. ☐ The specification is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). ☐ All ☐Some* None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)). *Certified copies not received: _____ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) X Notice of References Cited, PTO-892 ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). ☐ Interview Summary, PTO-413 ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 8, 11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "method" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is not clear to what method is the applicant referring.

The term "synergistically-effective amount" in claim 11 is a relative term which renders the claim indefinite. The term "synergistically-effective amount" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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4. Claims 1-15 rejected under 35 U.S.C. 102(a) as being anticipated by Beirsdorf AG DE 19753983 (abstract.)

The instant claims are directed to compositions comprising an amount of isoquercitrin, a carrier, a UVA or UVB blocker, and a synergistically effective amount of a secondary agent such as ascorbic acid.

DE patent disclose cosmetic compositions comprising isoquercitrin, a UV blocker and a secondary agent such as ascorbic acid (see abstract.) Thus, DE patent meets the limitations set forth in the instant claims.

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.
- 5. Claims 1-10, 12-15 rejected under 35 U.S.C. 102(e) as being anticipated by Gers-Barlag et al US Patent 5,952,391.

The instant claims are directed to compositions comprising an amount of isoquercitrin, a carrier, a UVA or UVB blocker.

Gers-Barlag et al disclose flavone derivative containing compositions comprising isoquercitrin or quercetin, a suitable carrier such as glycerol stearate or glycerol or ethanol, a UV blocker agent such as dibenzoylmethane or TiO₂ (see abstract, col 14-16.) Thus, Gers-Barlag et al meet the limitations set forth in the instant claims.

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-15 rejected under 35 U.S.C. 103(a) as being unpatentable over Gers-Barlag et al US Patent 5,952,391.

The instant claims are directed to compositions comprising an amount of isoquercitrin, a carrier, a UVA or UVB blocker, and a synergistically effective amount of a secondary agent such as ascorbic acid.

The teachings of Gers-Barlag et al US Patent 5,952,391 are discussed above. More specifically Ger-Barlag teach that their light protection formulations have higher stability against decomposition under the effect of light, particularly UV light; suggesting the synergistic effect of

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isoflavanoid compounds (see col 8 lines 55-67.) Even further, Ger-Barlag teach the addition of other antioxidant components such as carotenoids (col 10 line15-16), Vitamin E (col 10 line 41), Vitamin C, and Vitamin A (see col 10, lines 40-45.) Therefore, although Gers-Barlag et al do not specifically teach the incorporation of a secondary agent that provides a synergistic activity, he suggests the addition of a secondary agent of choice into their compositions; accordingly, it would have obvious to one of ordinary skilled in the art at the time of invention to add a secondary agent to the isoquercitrin composition such as Vitamin C or Vitamin A etc.. taught by Gers-Barlag, and optimize the suitable concentrations of isoquercitrin and a secondary agent, to prepare a flavonoid containing formulation that provides suitable skincare and dermetological light protection properties.

8. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gers-Barlag et al US Patent 5,952,391 in view of Bean US Patent 4,132,782, and Beirsdorf AG DE 19753983 (abstract.)

The instant claims are directed to compositions comprising an amount of isoquercitrin, a carrier, a UVA or UVB blocker, and a synergistically effective amount of a secondary agent such as ascorbic acid.

The teachings of Gers-Barlag et al US Patent 5,952,391 and Beirsdorf AG DE 19753983 are discussed above. Bean teaches flavonoid containing compositions that has antiviral properties against herpes simplex virus.

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Although Gers-Barlag et al do not specifically teach the incorporation of a secondary agent that provides a synergistic activity, he suggests the addition of a secondary agent of choice into their compositions (see col 10 line 10-55.) DE patent, further, teach various formulations of such compositions containing isoquercitrin. Finally, the antiviral properties of flavonoid containing compounds such as isoquercitrin are well described in the art; as taught by Bean. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose "the idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, it would have obvious to one of ordinary skilled in the art at the time of invention to add a secondary agent to the isoquercitrin composition of Gers-Barlag, as taught by DE patent, and optimize the suitable antiviral concentration of isoquercitrin; as suggested by Bean, to prepare a flavonoid containing compositions that provides suitable antiviral activity.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the

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status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs 7/30/2000

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